

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Peter A. Koopman, et al. **Examiner:** TO BE ASSIGNED

Serial No.: TO BE ASSIGNED **Art Unit:** TO BE ASSIGNED

Filed: Herewith **Docket:** 10981AZ

For: SOX-9 GENE AND PROTEIN
AND USE IN THE REGENERATION
OF BONE OR CARTILAGE **Dated:** July 20, 2001

Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

In connection with the filing of the above-identified application, kindly enter the following preliminary amendments.

IN THE CLAIMS:

Please cancel claims 1-6 without prejudice.

Please amend claims 7-10 to read as follows:

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I hereby certify that this Preliminary Amendment is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Assistant Commissioner of Patents and Trademarks, Washington, DC 20231.

Dated: July 20, 2001

Janet Grossman
Janet Grossman

7. (Amended) A method of regeneration of bone or cartilage by administration of a DNA molecule, wherein said DNA molecule comprises a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 18; (2) a nucleotide sequence having at least about 79% identity to SEQ ID NO: 18 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 18 under standard hybridization conditions and encodes a SOX-9 polypeptide.

8. (Amended) A method of regeneration of bone or cartilage by administration of a DNA molecule, wherein said DNA molecule comprises a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 20; (2) a nucleotide sequence having at least about 79% identity as SEQ ID NO: 20 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 20 under standard hybridization conditions and encodes a SOX-9 polypeptide.

9. (Amended) A method of regeneration of bone or cartilage by administration of a recombinant protein, wherein said protein is encoded by a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 18; (2) a nucleotide sequence having at least about 79% identity to SEQ ID NO: 18 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 18 under standard hybridization conditions and encodes a SOX-9 polypeptide.

10. (Amended) A method of regeneration of bone or cartilage by administration of a recombinant protein, wherein said protein is encoded by a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 20; (2) a nucleotide sequence having at least about 79% identity as SEQ ID NO: 20 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence

which hybridizes to SEQ ID NO: 20 under standard hybridization conditions and encodes a SOX-9 polypeptide.

Please add the following claims:

11. The method of claim 7, wherein said DNA molecule comprises a nucleotide sequence as set forth in SEQ ID NO: 18.
12. The method of claim 7, wherein said DNA molecule comprises a nucleotide sequence having at least about 79% identity to SEQ ID NO: 18 and coding for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 19 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 19.
13. The method of claim 7, wherein said DNA molecule hybridizes to SEQ ID NO: 18 under standard hybridization conditions and codes for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 19 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 19.
14. The method of claim 8, wherein said DNA molecule comprises a nucleotide sequence as set forth in SEQ ID NO: 20.
15. The method of claim 8, wherein said DNA molecule comprises a nucleotide sequence having at least about 79% identity to SEQ ID NO: 20 and coding for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 21 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 21.
16. The method of claim 8, wherein said DNA molecule hybridizes to SEQ ID NO: 20 under standard hybridization conditions and codes for a SOX-9 polypeptide, and wherein said

SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 21 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 21.

17. A method of regeneration of bone or cartilage by administration of a recombinant protein, wherein said protein comprises an amino acid sequence as set forth in SEQ ID NO: 19 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 19.

18. A method of regeneration of bone or cartilage by administration of a recombinant protein, wherein said protein comprises an amino acid sequence as set forth in SEQ ID NO: 21 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 21.

REMARKS

Claims 1-6 have been canceled without prejudice. Applicants reserve the right to pursue the subject matter of the canceled claims in a continuation application.

Claim 7, which depended from claim 1, has been amended essentially to incorporate the delineations of claim 1. Claim 8, which depended from claim 2, has been amended essentially to incorporate the delineations of claim 2. Claim 9, which depended from claim 3, has been amended essentially to incorporate the delineations of claim 3. Claim 10, which depended from claim 4, has been amended essentially to incorporate the delineations of claim 4. It is respectfully submitted that the amendments to claims 7-10 are supported by the specification and original claims 1-4.

Added claims 11-13 depend from claim 7 and further delineate the nucleotide sequence recited in claim 7. Support for claims 11-13 is found throughout the specification and in original claim 1.

Added claims 14-16 depend from claim 8 and further delineate the nucleotide sequence recited in claim 8. Support for claims 11-13 is found throughout the specification and in original claim 2.

Added claims 17-18 are directed to methods of regeneration of bone or cartilage by administration of a recombinant protein. The subject matter of claims 17-18 is supported by the specification and original claims 3-4 and 9-10.

Applicants respectfully submit that the foregoing amendments do not introduce new subject matter. Attached hereto is a marked-up copy of the amendment to the claims, captioned "Version with Markings to Show Changes Made."

It is respectfully submitted that the present case is in condition for examination on merits, which action is earnestly solicited.

Respectfully submitted,



Frank S. DiGilio
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER
400 Garden City Plaza
Garden City, New York 11530
(516) 742-4343
FSD/XZ:ab

Serial No.: TO BE ASSIGNED

Version with Markings to Show Changes Made

In the Claims:

Please cancel claims 1-6 without prejudice.

Please amend claims 7-10 as follows:

7. (Amended) A method of regeneration of bone or cartilage by administration of a DNA molecule, [as claimed in claim 1] wherein said DNA molecule comprises a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 18; (2) a nucleotide sequence having at least about 79% identity to SEQ ID NO: 18 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 18 under standard hybridization conditions and encodes a SOX-9 polypeptide.

8. (Amended) A method of regeneration of bone or cartilage by administration of a DNA molecule, [as claimed in claim 2] wherein said DNA molecule comprises a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 20; (2) a nucleotide sequence having at least about 79% identity as SEQ ID NO: 20 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 20 under standard hybridization conditions and encodes a SOX-9 polypeptide.

9. (Amended) A method of regeneration of bone or cartilage by administration of a recombinant protein, [as claimed in claim 3] wherein said protein is encoded by a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 18; (2) a nucleotide sequence having at least about 79% identity to SEQ ID NO: 18 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 18 under standard hybridization conditions and encodes a SOX-9 polypeptide.

10. (Amended) A method of regeneration of bone or cartilage by administration of a recombinant protein, [as claimed in claim 4] wherein said protein is encoded by a nucleotide sequence selected from the group consisting of: (1) SEQ ID NO: 20; (2) a nucleotide sequence having at least about 79% identity as SEQ ID NO: 20 and coding for a SOX-9 polypeptide; and (3) a nucleotide sequence which hybridizes to SEQ ID NO: 20 under standard hybridization conditions and encodes a SOX-9 polypeptide.

Please add the following claims:

11. The method of claim 7, wherein said DNA molecule comprises a nucleotide sequence as set forth in SEQ ID NO: 18.

12. The method of claim 7, wherein said DNA molecule comprises a nucleotide sequence having at least about 79% identity to SEQ ID NO: 18 and coding for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 19 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 19.

13. The method of claim 7, wherein said DNA molecule hybridizes to SEQ ID NO: 18 under standard hybridization conditions and codes for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 19 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 19.

14. The method of claim 8, wherein said DNA molecule comprises a nucleotide sequence as set forth in SEQ ID NO: 20.

15. The method of claim 8, wherein said DNA molecule comprises a nucleotide sequence having at least about 79% identity to SEQ ID NO: 20 and coding for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth

in SEQ ID NO: 21 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 21.

16. The method of claim 8, wherein said DNA molecule hybridizes to SEQ ID NO: 20 under standard hybridization conditions and codes for a SOX-9 polypeptide, and wherein said SOX-9 polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 21 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 21.

17. A method of regeneration of bone or cartilage by administration of a recombinant protein, wherein said protein comprises an amino acid sequence as set forth in SEQ ID NO: 19 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 19.

18. A method of regeneration of bone or cartilage by administration of a recombinant protein, wherein said protein comprises an amino acid sequence as set forth in SEQ ID NO: 21 or an amino acid sequence having at least about 93.5% identity to SEQ ID NO: 21.